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ORIGINAL ARTICLE

Comparison of the size 3 and size 4 ProSeal™ laryngeal mask airway in anesthetized, non-paralyzed women: a randomized controlled trial

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Abstract
Purpose Based on experimental results, various authors have advocated a size 4 ProSeal™ laryngeal mask airway (PLMA) in preference to a size 3 PLMA for women given a neuromuscular blocking agent because the larger size provided a better airway seal. However, spontaneously breathing patients may be ventilated adequately with a lower seal pressure than that needed for mechanical ventilation. Therefore, a smaller size might be preferable as its reduced bulk possibly induces less mucosal damage in non-paralyzed patients.
Methods A total of 152 females undergoing general anesthesia for short outpatient gynecological surgeries were randomly allocated in equal numbers to insertion of a size 3 or 4 PLMA. The insertion time, success rate, seal pressure, hemodynamic variables, and complications, such as blood staining and sore throat, were evaluated.
Results The incidence of blood staining was lower with the size 3 PLMA compared to the size 4 PLMA (18 vs. 36 %; $P = 0.028$). Compared with the size 3 LMA, the size 4 PLMA resulted in higher fluctuations in both blood pressure ($P = 0.003$) and heart rate ($P = 0.01$). The insertion time was shorter with the size 3 PLMA (9 vs. 16 s; $P < 0.001$). The airway seal pressure with the size 3 PLMA, although lower than that of the size 4 PLMA (23 vs. 28 cmH_2O; $P = 0.001$), was sufficient for spontaneous ventilation.
Conclusions Due to the reduced incidence of mucosal injury and greater hemodynamic stability, the size 3 PLMA may be preferable to the size 4 PLMA for non-paralyzed females.

Keywords Laryngeal mask airway · Airway management · General anesthesia · Non-paralyzed patients

Introduction

The ProSeal™ laryngeal mask airway (PLMA; The Laryngeal Mask Company, Victoria, Seychelles), an upgraded modification of the classic laryngeal mask airway (LMA) [1–3], has been used effectively in various procedures and patient groups [4, 5] and assessed in numerous recent studies [5–10]. Despite its widespread use, the PLMA is associated with several complications, such as sore throat and oropharyngeal bleeding [5]. The most commonly reported disadvantage is the presence of blood on the device after removal [3], which occurs with an incidence of 4–40 % [11–15], suggesting that oropharyngeal injury is common with PLMA use.

Theoretically, airway mucosal injury might occur more frequently with a larger sized PLMA than with a smaller one. Therefore, size selection is important in the clinical setting when a PLMA is used. The authors of previous studies have recommended the size 4 PLMA over the size 3 one for women due to the better seal [16, 17]. In these studies, the patients were given neuromuscular blocking agents. However, the use of muscle

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relaxants for inserting LMAs is often avoided to facilitate recovery, especially in short procedures and in the setting of ambulatory anesthesia [18], or when neuromuscular blockade is contraindicated [19]. Since neuromuscular blockade can reduce the tone of the pharyngeal musculature, thereby creating different conditions for inserting a LMA in patients with intact neuromuscular transmission [20], the findings of studies in which muscle relaxants were used might not apply to PLMA insertion in non-paralyzed patients. To date, no published studies have compared the efficacy of PLMA size in the absence of muscle relaxants.

Several studies have focused on the appropriate size selection of the LMA. The authors of one study concluded that size 4 PLMA is preferable for women [16]. In another study, both sex- and weight-based (size 3 for weight <50 kg, size 4 for weight 50–70 kg, and size 5 for weight >70 kg) size selection of the PLMA were comparably effective, but the sex-based formula (size 4 for women) provided a better seal [21]. For Asian women, the size 4 PLMA has been recommended [17]. In a study with classic LMA, both size 4 and 5 LMAs were suitable for women [22]. On the basis of previous publications, sex-based size selection (size 4 or 5 for women) of LMA was recommended in a review article [23]. However, size 4 LMAs often protruded into the mouth in short statured women [24]. In all these studies, neuromuscular blocking agent was used for LMA insertion. There are studies in which neuromuscular blocking agents were not used. In one of these studies, size 4 LMA was recommended for women owing to higher seal pressure [25]. In the other study, size 3 LMA accompanied lower incidence of sore throat than size 4 [20]. These study used the classic LMA not PLMA. The ProSeal and classic LMAs differ in ease of insertion and complications; the PLMA is more difficult to insert than the classic LMA because of its larger cuff and lack of a backplate [26]. Blood staining occurs more frequently with the PLMA than with the classic LMA [27].

In this context, we considered that the appropriate size of the PLMA in a non-paralyzed patient had not yet been clearly determined and thus deserved further study. We therefore compared the size 3 PLMA with the size 4 PLMA in non-paralyzed female patients in terms of oropharyngeal injury, since this type of injury one of the most common complications associated with the PLMA [3]. We hypothesized that in anesthetized, non-paralyzed women, the size 3 PLMA cause less mucosal damage that the size 4 PLMA, as indicated by blood on the cuff (primary outcome). Additional variables associated with PLMA insertion and complications were also measured as exploratory data to estimate the efficacy of each PLMA size.

Methods

This randomized controlled study was approved by the Institutional Review Board of Seoul National University Bundang Hospital, Seongnam, Korea (No. B-1003/096-008) on 7 April 2010 and was registered at clinicalTrials.gov (NCT01184677). Written informed consent was obtained from all participants. The study enrolled 154 females (age 18–80 years; American Society of Anesthesiologists physical status I–II) who were scheduled for short outpatient gynecological procedures under general anesthesia. Exclusion criteria included known or predicted difficult airway, recent sore throat, recent upper airway infection, inability to open the mouth more than 2.5 cm, risk of aspiration, and body mass index of >35 kg/m^2. As a preoperative airway evaluation, the Mallampati score was assessed by asking the patient (in a sitting posture) to open her mouth and protrude her tongue as far as possible [28].

Patients were randomly allocated to receive either a size 3 or size 4 PLMA. Briefly, either "size 3" (n =77) or size 4" (n = 77) was written on a piece of paper that was then placed in an opaque envelope by a research assistant and sealed. The envelopes were then well shuffled in a box. Pulse oximetry and electrocardiography were determined and the baseline mean arterial pressure (MAP) and heart rate (HR) recorded. The patients were pre-medicated with intravenous midazolam at 0.03 mg/kg. Anesthesia was induced using a continuous infusion of propofol (plasma target concentration 7 μg/ml) via a target-controlled infusion device (Orchestra; Fresenius-Vial, Brezins, France), and alfentanil 5 μg/kg was administered intravenously. MAP and HR were measured when conditions were suitable for PLMA insertion (loss of eyelash reflex, jaw relaxation, absence of movement, and apnea) [26], as the pre-insertion MAP and HR. A nurse subsequently picked one of the opaque sealed envelopes and prepared the PLMA, with the indicated size number ("3" or "4") concealed on the mask with non-transparent black tape. A water-based lubricant gel without local anesthetic was applied to the posterior surface of the PLMA. The PLMA cuff was deflated fully before insertion. With the patient in the supine and "sniffing" position, a single anesthesiologist who had completed more than 500 PLMA insertions used the index finger insertion technique to place the device according to the manufacturer's instructions. The cuff was inflated to secure the airway, not exceeding the maximum clinical inflation volume [26]. An effective airway was confirmed by respiratory chest movement, a square-wave capnograph trace, and no audible leak during spontaneous breathing or during assisted ventilation in patients without adequate spontaneous respiration (no audible leak at peak airway pressures of ≥12 and ≤20 cmH_2O during assisted ventilation) [2, 26]. After establishing an effective airway,

the intra-cuff pressure was adjusted to maintain 60 cmH_2O. Airway seal pressure was defined as the maximum airway pressure ($\leq$40 cmH_2O) that did not allow an airway leak while the gas flow (3 L/min) was maintained with the expiratory valve of the ventilator circuit closed [29]. When placement failed after two attempts, the airway was managed as clinically indicated at the discretion of the anesthesiologist. Insertion time was defined as the time from grasping the device to the establishment of an effective airway. If the second attempt at insertion failed, then the insertion time was recorded as the time between picking up the PLMA and confirmation of an ineffective airway after the second insertion because excluding the failed cases from the results could erroneously decrease the mean value of the insertion time. MAP and HR immediately after the final attempt of PLMA insertion (i.e., after a maximum of two insertion attempts) were recorded as the post-insertion MAP and HR, respectively.

After PLMA insertion, anesthesia was maintained by continuous infusion of propofol (plasma target concentration 2–4 μg/ml) and 67 % nitrous oxide in oxygen. The patients received positive pressure ventilation until spontaneous respiration resumed. Records were kept of whether the patient required positive-pressure ventilation throughout the operation. Incidences of airway leak (defined as bubble formation or dislodgement of the lubricant gel that was placed in the proximal end of the drain tube [1], entrance of air into the stomach, as detected by epigastric auscultation [30], gastric insufflations, or audible leak at the mouth [29]), of failed ventilation (defined as oxygen saturation of <95 % or an inability to maintain an expired tidal volume of $\geq$8 ml/kg), and of other complications [regurgitation/aspiration (bilious secretions or particulate matter in the airway tube), laryngospasm (sudden-onset difficulty in mask ventilation, with or without paradoxical respiratory movements or inspiratory stridor, after PLMA insertion attempt), and cough/gag/retching/hiccup] that occurred from confirmation of effective PLMA insertion until the end of anesthesia were documented. The PLMA was removed after surgery as clinically indicated (spontaneous eye opening and adequate spontaneous respiration). The presence of blood on the laryngeal mask as a surrogate measure of mucosal injury was recorded. The postoperative analgesia regimen in the post-anesthesia care unit consisted of intravenous fentanyl 25–50 μg at the patient's request. Before discharge to the ward, the nurses asked the patient whether she had a sore throat or hoarseness. The research personnel who prepared the opaque sealed envelopes picked out the envelope and recorded study outcomes; the anesthesiologist who inserted the PLMA was unaware of the study and was not involved in other aspects of the study. Group allocations were concealed using codes until the completion of the statistical analysis. Only the nurse who prepared the PLMA and the anesthesiologist who inserted the PLMA were allowed to see the PLMA. However, the anesthesiologist was strongly encouraged not to pay attention to cuff size.

Statistical analysis

The primary outcome was the presence of blood on the PLMA. Calculation of sample size was based on preliminary data from ten patients in each group (unpublished). A difference of 50 % in the incidence of blood staining between the PLMA sizes 3 and 4 was considered to be clinically significant, based on an earlier study showing a 50 % increase in oropharyngeal bleeding during the use of a PLMA compared with a classical LMA [3]. We believed that if a smaller PLMA resulted in a bleeding incidence comparable with that of the classical LMA, then the use of a smaller size is warranted. With a type 1 error of 0.05 and a power of 0.9, and allowing for a 10 % drop-out rate, we calculated that 77 patients per group were required. The distribution of data was analyzed using the Kolmogorov–Smirnov test. Student's *t* test or the Mann–Whitney *U*-test (for skewed data) was used to compare the time for PLMA insertion, seal pressure, and pre-insertion hemodynamic variables. The rate of successful insertion and incidences of visible blood on the PLMA and other complications, and the rate of positive-pressure ventilation required throughout the operation were compared using a chi-square analysis or Fisher's exact test. Changes in HR and MAP at different time points within and between groups were analyzed using repeated-measures analysis of variance (ANOVA). A value of $P < 0.05$ indicated statistical significance.

Results

Of the 154 patients enrolled in the study from August 2010 to December 2011, two patients dropped out; consequently, data from 152 patients were analyzed (Fig. 1). Patients' characteristics are summarized in Table 1. In the size 3 and size 4 PLMA groups, 55 and 51 patients, respectively, were shorter than 160 cm, and 11 and 8 patients, respectively, required positive-pressure ventilation throughout the operation ($P = 0.62$). The total intraoperative opioid dosage was identical at 5 μg/kg of alfentanil in each patient. The postoperative opioid (fentanyl) consumption was comparable between the groups [mean $\pm$ standard deviation: 16 $\pm$ 18 (size 3 group) vs. 17 $\pm$ 19 (size 4 group) μg; $P = 0.75$]. The insertion results and complications are shown in Table 2. The rates of initial and overall successful insertion were comparable between the groups ($P > 0.05$). Insertion time was shorter in the size 3 group than in the size 4 group

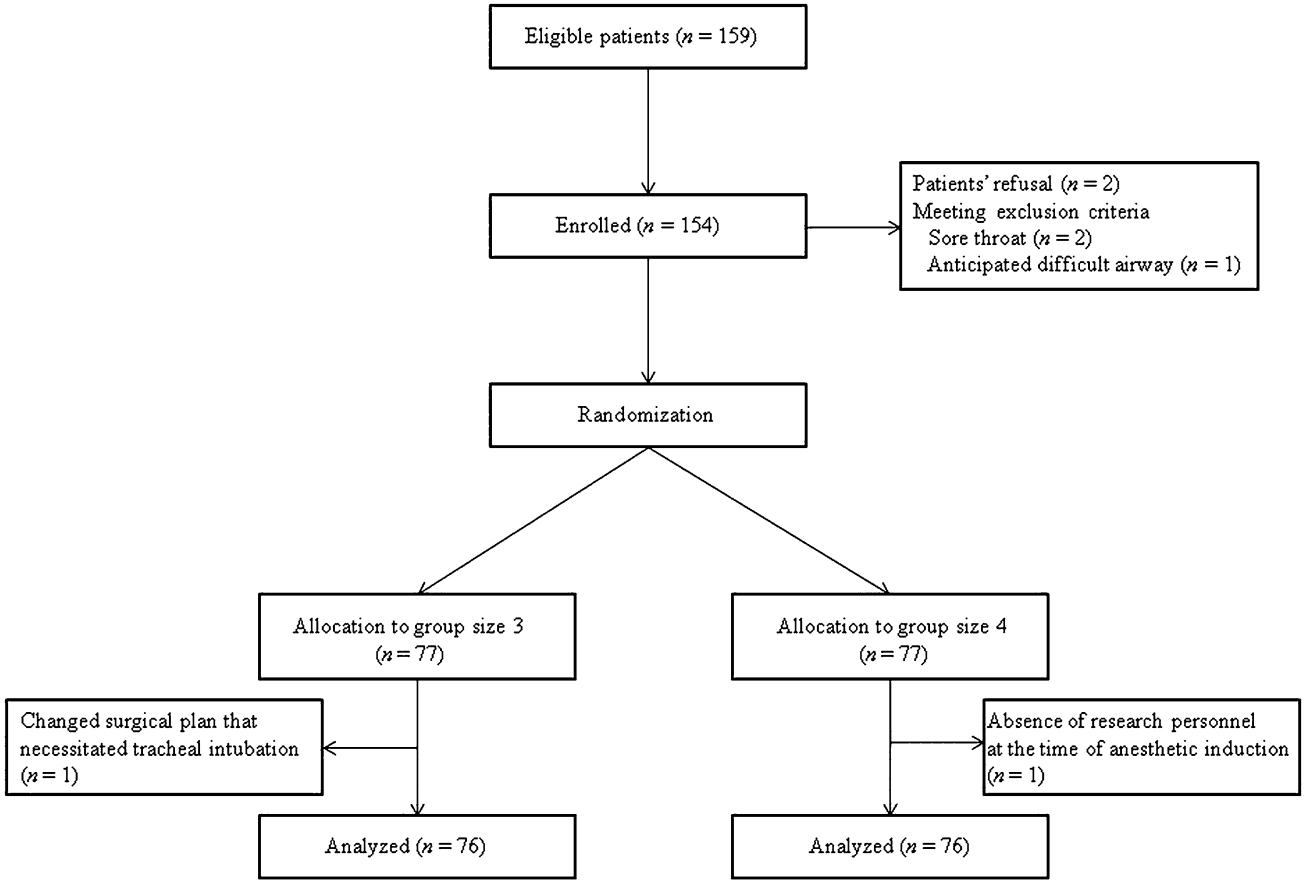

Fig. 1 Flow chart of patient enrolment and allocation

Table 1 Patient characteristics

Characteristic	Size 3 ($n = 76$ patients)	Size 4 ($n = 76$ patients)
Age (years)	42 (35–46)	46 (38–51)
Weight (kg)	58 ± 8	56 ± 8
Height (cm)	159 ± 5	158 ± 5
Mallampati score (I/II/III)	63/13/0	65/11/0
Duration of surgery (min)	34 ± 14	32 ± 14
Baseline MAP (mmHg)	67 ± 11	66 ± 11
Baseline HR (beats/min)	67 ± 12	66 ± 9

Data are presented as the median with the interquartile range (IQR) in parenthesis, as the mean ± standard deviation (SD), or as a number, where appropriate

MAP mean arterial pressure; *HR* heart rate

[median (interquartile range): 9 (8–12) vs. 16 (10–21) s, respectively; $P < 0.001$]. Oropharyngeal leak pressure was higher in the size 4 group than in the size 3 group (28 ± 6 vs. 23 ± 6 mmHg, respectively; $P = 0.001$). HR was elevated in both groups after the insertion of the PLMA compared with baseline ($P < 0.001$). However, the HR in the size 3 group did not significantly change ($P > 0.05$), whereas that in the size 4 group increased significantly ($P < 0.001$) following PLMA insertion. Greater changes between the pre- and post-insertion HR and MAP occurred in the size 4 group compared to the size 3 group, as indicated by repeated-measures ANOVA. The incidence of airway leak was comparable between the groups ($P > 0.05$). No failed ventilation was observed based on confirmation of effective PLMA insertion until the end of anesthesia in both groups. The size 3 group had a significantly lower incidence of mucosal injury, as evidenced by the presence of blood on the PLMA, than the size 4 group ($P = 0.028$). The incidence of intraoperative complications associated with PLMA insertion other than blood staining was similar between the two groups ($P > 0.05$).

Discussion

The results of our study show that the size 3 PLMA was associated with a lower incidence of blood detected on the device and that the ventilation it provided in anesthetized, non-paralyzed women was comparable to that of the size 4 PLMA. Visible blood on the PLMA has been used in

numerous studies as a surrogate marker for oropharyngeal mucosal injury or trauma [14–17, 21, 31, 32]. Airway injury during anesthesia can be a source of patient discomfort and morbidity, as well as of medico-legal conflicts [33]. Hence, it is important to secure the airway with as little trauma as possible. In this regard, the size 3 PLMA is preferred to the size 4 PLMA in non-paralyzed patients because it is less traumatic.

The insertion time was longer for the size 4 PLMA than for the size 3 PLMA, suggesting a greater difficulty in inserting the former, although the overall success rate was similar. This result is in accordance with those reported previously showing that larger laryngeal masks were associated with a more difficult and traumatic insertion (size 4 vs. size 5 in women [16] and men [17]). The PLMA is difficult to insert due to a lack of space for maneuvering the PLMA in the oral cavity [17] and because the PLMA cuff can easily hit the oropharyngeal arch [1]. These disadvantages are amplified with the use of larger sizes of PLMA. In addition, the larger mask has a wider surface area in contact with the oropharynx, which might increase friction and predispose to oropharyngeal trauma, particularly in patients breathing spontaneously. In this context, a larger cuff is likely to be the cause of the higher oropharyngeal bleeding rate associated with the size 4 PLMA. The size 3 PLMA produced less fluctuation in hemodynamic variables following insertion as compared with the size 4 cuff, possibly because of an easier insertion and less trauma, given comparable anesthetic depth between the two groups, as indicated by the similar patient characteristics (Table 1), identical induction dose of anesthetic agents, and comparable MAP and HR measured immediately before PLMA insertion (Table 2).

In contrast to our results, in a previous study the occurrence of mucosal injury was comparable between the size 3 and 4 PLMA in paralyzed females, with the blood-staining rate being slightly higher for the size 4 PLMA (18 vs. 21 %, respectively), although the difference was not significant ($P > 0.05$) [16]. In our study, the incidence of blood detection was 18 and 36 % for the size 3 and 4 PLMA, respectively. This inconsistency between the two studies might be due in part to the smaller sample size ($n = 29$–30 in each group) recruited in the previous study, but the discrepancy between 21 and 36 % is not sufficiently explained by a difference in sample size only. Another plausible explanation is that muscle relaxation reduced muscle tone, which might enable the pharyngeal musculature to better accommodate a larger mask, which in turn led to easier insertion of the PLMA in paralyzed patients [20]. The reported incidence rates of bleeding following PLMA insertion are widespread: 5.7–5.9 % [21], 8 % [14, 34], 13 % [17], 15 % [27], 15–2 % [16], 30 % [35], 31 % [32], 3 % [26], and 40 % [15]. Accordingly, a bleeding incidence of 18 % with the size 3 PLMA in our study is lower [15, 26, 32, 35] or similar [16, 17, 27] to that reported in some studies, but higher than that reported in other studies [14, 21, 34]. This variability could in part be attributable to our omission of a neuromuscular blocking agent and individual operator roughness during insertion. Inadequate anesthetic depth could also increase the bleeding incidence. However, the incidence of cough/gag/retching/hiccup was only 2–3 %, and the changes in MAP and HR following insertion were 1.5–15.6 %, implying that the anesthetic depth in our study was relatively adequate for PLMA insertion using the digital insertion technique.

Table 2 ProSeal laryngeal mask airway insertion results and complications in patients

Parameter	Size 3 ($n = 76$ patients)	Size 4 ($n = 76$ patients)	P value
Success rate			
First attempt	67 ± 88	64 ± 84	0.48
Second attempt	3 ± 4	7 ± 9	0.26
Failed	6 ± 8	5 ± 7	0.75
Insertion time (s)	9 (8–12)	16 (10–21)	<0.001
Seal pressure (cmH_2O)	23 ± 6	28 ± 6	0.001
Hemodynamic variable			
MAP pre-insertion (mmHg)	62 ± 11	64 ± 10	0.24
MAP post-insertion (mmHg)	66 ± 13	74 ± 12	0.003[a]
HR pre-insertion (beats/min)	67 ± 9	65 ± 9	0.17
HR post-insertion (beats/min)	68 ± 10	69 ± 10	0.01[a]
Complications			
Airway leak	5 ± 6.6	3 ± 3.9	0.72
Failed ventilation	0 ± 0	0 ± 0	1
Regurgitation/aspiration	0 ± 0	0 ± 0	1
Laryngospasm	1 ± 1	2 ± 3	1
Cough/gag/retching/hiccup	2 ± 3	3 ± 4	1
Blood staining	14 ± 18	27 ± 36	0.028
Sore throat	18 ± 24	26 ± 34	0.21
Hoarseness	7 ± 9	5 ± 7	0.76

Pre- and post-insertion hemodynamic variables were measured immediately before and after insertion of the ProSeal™ laryngeal mask airway (PLMA), respectively

Data are presented as the median with the IQR in parenthesis or as the mean ± SD

[a] P values between the groups for changes in MAP or HR over time (from the time point of pre-insertion to post-insertion) were obtained by repeated-measures analysis of variance

In contrast to our findings, the size 4 PLMA has been advocated for women due to its higher oropharyngeal leak pressure [16]. A better seal may be needed during laparoscopic surgeries that require insufflation gas in which airway pressure is concomitantly raised with increased intra-abdominal pressure, as well as in other situations where airway resistance is increased pathologically. However, the lungs of most healthy patients can be ventilated with a seal pressure of 20 cmH_2O [3]. We found that this level of seal pressure was successfully obtained with the size 3 PLMA, which gave a mean seal pressure of 23 cmH_2O. Moreover, the better seal obtained with the larger size PLMA has been regarded as clinically unimportant, as evidenced by the absence of a difference in gas exchange between two groups in a trial [21] that compared sex- and weight-based PLMA size selection criteria using various respiratory parameters. Although we did not assess such detailed ventilation parameters, similar incidences of airway leak and of adequate ventilation between the groups in our study suggest that the improved seal in the size 4 PLMA did not provide those patients with additional benefits. Based on experimental evidence showing that higher leak pressure is the sole primary basis for supporting the use of a larger size PLMA [16, 17, 21], comparable ventilation outcomes between the size 3 and 4 PLMA diminish the clinical significance of a higher seal pressure and hence lessen the need for a larger size PLMA in non-paralyzed patients. In this context, the advantages and effectiveness of the size 3 PLMA observed among our study cohort suggest a different perspective on PLMA-size selection, as no study to date has refuted the report [16] which recommends the size 4 PLMA for women.

It is possible that the incidence of mucosal injury could be partially attributed to individual operator roughness during insertion. However, successful insertion rate, insertion time, and sore throat incidence among our study cohort were similar to those reported previously [15, 16, 26], suggesting that the insertion skill of the anesthesiologist in our study did not substantially deviate from that of other experienced PLMA users, although the various studies cannot be directly compared. Moreover, insertion was performed by a single experienced anesthesiologist in this study. Additionally, factors affecting PLMA insertion other than its size, such as anesthetic agents, insertion technique, and positioning of the patient, were controlled and equivalent. Therefore, the different incidence of blood-tinged PLMA between the two groups is most likely due to the different sizes of the PLMA.

Size selection could be influenced by patient's height. In one study, the size 4 LMA was seen in the mouth more frequently than the size 3 in females shorter than 160 cm [24]. In our study, 55 and 51 patients in the size 3 and size 4 PLMA group, respectively, were shorter than 160 cm; for these patients the size 3 PLMA might be the better choice based on their short stature. However, size selection of PLMA may not be solely dependent on a patient's height because in previous studies size 4 has been the preferred choice for women with even a slightly smaller mean body size [16, 17, 21] than that of the women in our study [152–156 vs. 158–159 cm (our study); 52–56 vs. 56–58 kg (our study)].

There were some limitations to this study. First, complete operator blindness regarding the PLMA size was not possible, although the operator tried not to pay attention to the cuff size or the size number on the PLMA, which was concealed with tape. However, all of the study variables, including insertion time and hemodynamic status, were recorded by personnel who were blind to the PLMA size. It is possible that the nurses who recorded the presence of blood on the PLMA noticed the size, but they were unaware of the study protocol. Second, the study subjects were all females. Further studies are required to determine the appropriate PLMA size for spontaneously breathing males. Third, blood on the PLMA might not reflect the incidence of mucosal injury, which does not accompany blood, although blood has been often used as surrogate marker of mucosal injury [14–17, 21, 31, 32]. Fourth, although the changes in HR between the pre- and post-insertion time points were significantly greater in the size 4 group, the apparently similar mean post-insertion HR values between the groups (68 vs. 69 beats/min) might reduce the clinical significance of this finding. Fifth, the present results have limited application to longer surgeries. However, the short procedures enrolled in this study are common clinical settings in which PLMAs are used without neuromuscular blocking agents. Sixth, all of the insertions were conducted with the digital technique; consequently, the results of this study might not be applicable to PLMA insertion using other techniques, such as the 90° rotation [15] or bougie-guided [11] techniques. However, we considered the digital insertion technique to be a commonly used PLMA insertion method in clinical practice because the technique is specified in the manufacturer's instructions. Seventh, the findings of this study are from an Asian patient population, and Asians have a relatively small body size; therefore, extrapolation of these results to a study cohort of larger patients requires caution. Finally, we reported only the incidence of postoperative sore throat, and not its severity, which is commonly assessed using a 4-point scale [36]. Evaluation of the severity might have better elucidated the influence of PLMA size on postoperative sore throat.

In conclusion, based on our results the size 3 PLMA might be preferable to the size 4 PLMA for non-paralyzed women because of the reduced incidence of mucosal injury and greater hemodynamic stability.

Conflict of interest None.

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